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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,217	11/25/1997	CHRISTOPHER C. BENZ	02307E-07111	4060

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/978,217	BENZ ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,16-18,21-26,71,79 and 82-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88 and 89 is/are allowed.
- 6) ☒ Claim(s) 1-4,6-13,16-18,21-26,71,79 and 82-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 11/24/2003 is acknowledged. Claims 1 and 16 were amended.
2. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained and New Grounds of Rejection:

4. The rejection of claims 1-4, 6-9, 16-19 and 21-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained, and applied to claim 79.

Although the amendment to claims 1 and 16 appears to provide specific hybridization conditions, it is not clear that the recited conditions refer to the conditions under which hybridization occurs or whether the recited conditions refer to the conditions of the wash step. A review of the specification to find support for the amendment to claims 1 and 16 shows that the recitation "comprising 65°C in 0.2 x SSC" is only used in reference to the wash conditions of a Northern hybridization procedure (page 74, lines 1-7). This rejection would be obviated if the claims were to be amended to recite "stringent hybridization conditions comprising washes at 65°C in 0.2 x SSC".

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5. Claims 1, 4, 6-13, 16, 21-26, 71, 79, and 82-85 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation that the nucleic acid must hybridize under undefined conditions to a target nucleic acid. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The rejections are maintained for the reasons of record. Applicant's arguments are unpersuasive because applicant fails to establish that the proposed functional limitation "encoding a transcription factor" limits the breadth of the claimed genera to inventions for which the disclosure of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 15, and SEQ ID NO: 16 are representative embodiments. The specification fails to provide a definition of the term "transcription factor", and defines the term "ESX transcription factors" as including non-functional variants. Therefore, the term "transcription factor" does not provide a functional limitation for the claimed inventions. Transcription factors encompass a broad range of

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structurally and functionally different compounds. For example, Lodish (Molecular Cell Biology, Ed. H. Lodish et al., Scientific American Books, New York, 1995; pages 442) teaches that eukaryotic transcription factors may either stimulate or repress transcription. Lodish also teaches (pages 445-453) that transcription factors as a group comprise a variety of protein structures (homeodomain proteins, zinc-finger proteins, winged-helix proteins, to name some examples) in both the DNA binding domains and in the activation domains. Furthermore, the specification appears to include non-functional and mutated forms of ESX transcription factors as examples of ESX transcription factors that are encompassed by the term “ESX transcription factor” (see pages 15-16).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). The claims encompass nucleic acids that encode mutated variants, non-functional forms and splice-variants of the polypeptide that consists of the amino acid sequence of SEQ ID NO: 2, for which not one example has been provided in the specification, and for which the sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 15, and SEQ ID NO: 16 are not representative embodiments. The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, given that the specification has only described SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 15, and SEQ ID NO: 16. Therefore, a significant portion of the claimed genus has not been described, and one of skill in the art would not find that

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applicant was in possession at the time of filing of claims to full genus of nucleic acids encompassed by either claim 1 or 16. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

This rejection would be obviated for claim 1 (and its dependent claims) if claim 1 were amended as directed in #4 above, **and** if “transcription factor” was replaced with the phrase “transcription factor that binds to and transactivates the Her-2/neu Ets response element”. The specification does not appear to provide teachings that the murine sequence of claim 16 binds to and transactivates the Her-2/neu Ets response element.

6. The rejection of claims 1, 2, 6-13, 21-26, 79, and 82-87 under 35 U.S.C. 102(e) as being anticipated by Kola et al, (U.S. Patent 5,789,200; issue Aug. 4, 1998; effective filing date Oct. 31, 1996) is maintained for the reasons of record, and applied to claim 16.

Claim 16 is rejected (as were previously rejected claims 21-26, which depend from claim 16) because it is broadly interpreted to read on nucleic acids that comprise encode fragments of a transcription factor having the amino acid sequence consisting of the amino acid sequence of SEQ ID NO: 2, which is the same sequence as the polypeptide of Kola.

Applicant presents no specific arguments why this rejection should be withdrawn. Applicant's comments with regard to providing a declaration under 37 C.F.R. 1.131 are noted. However, applicant's attention is drawn to MPEP 2308.01 that instructs applicant to file a statement under 37 C.F.R. 1.608(a) or 37 C.F.R. 1.608(b) when a patent claims the same invention as what is claimed in an application to another. See also MPEP 2138.03: Interference

practice operates to the exclusion of ex parte practice under 37 CFR 1.131 which permits an applicant to show an actual date of invention prior to the effective date of a patent or literature reference applied under 35 U.S.C. 102(a) or (e), as long as the patent is not a domestic patent claiming the same patentable invention. Ex parte Standish, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Inter. 1988) (An application claim to the “same patentable invention” claimed in a domestic patent requires interference rather than an affidavit under 37 CFR 1.131 to antedate the patent. The term “same patentable invention” encompasses a claim that is either anticipated by or obvious in view of the subject matter recited in the patent claim.). Subject matter which is available as prior art only under 35 U.S.C. 102(g) is by definition made before the applicant made his invention and is therefore not open to further inquiry under 37 CFR 1.131.

7. Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the amendment adding the recitation “comprising 65°C in 0.2 x SSC” to claims 1 and 16 introduces new matter into the specification.

As a preliminary matter, it is noted that applicants failed to indicate where in the specification specific support for the amendment to claims 1 and 16 may be found.

A review of the specification to find support for the amendment to claims 1 and 16 shows that the recitation “comprising 65°C in 0.2 x SSC” is only used in reference to the wash conditions of a Northern hybridization procedure (page 74, lines 1-7). The teachings in the

specification concerning the hybridization conditions are set forth on pages 13-14, and indicate that stringent conditions are defined in terms of ionic strength, temperature and pH and in terms of the length of the probe. No where in the teachings of pages 13-14 does the specification set forth that a stringent conditions may be specifically defined by the recitation "comprising 65°C in 0.2 x SSC". Therefore, it appears that the amendment to claims 1 and 16 constitutes new matter, and one of skill in the art would not conclude that applicant was in possession of the claimed invention at the time of filing.

Conclusion

Claims 88 and 89 are allowable. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-87 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Anne L. Holleran
Patent Examiner
March 5, 2004


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